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EXAMINER	
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ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/730,873	SINGHAL ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-34,36-45,47-49,51,53-56 and 60-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-34,36-45,47-49,51,53-56 and 60-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/06, 08/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

2. Applicant's submission filed on June 16, 2006 has been entered. Claims 9, 35, 46, 50, 52 and 57-59 have been cancelled. Claims 1-8, 10-34, 36-45, 47-49, 51, 53-56 and 60-66 are pending.

Information Disclosure Statement

3. The information disclosure statements (IDS) submitted on June 16, 2006 and August 15, 2006 have been acknowledged and are being considered by the Examiner.

Claim Objections

4. Claims 15, 32 and 39 are objected to because of the following informalities: there appears to be inadvertent typographical errors existing in the claims.

As to Claim 15, the Examiner suggests changing the third line from "and provides the sloped transition" to read "and provides a sloped transition" so as to avoid an antecedent basis problem.

As to Claim 32, the Examiner suggests revising the last three lines of the claim to read ""component that at least partially encapsulates each of the housings and a second component that is positioned to surround at least one of the housings, wherein the first component comprises an elastomeric material and the second component comprises a non-elastomeric material" in order to clarify the claim language.

As to Claim 39, the Examiner suggests changing the second line of the claim from "edge of first component" to read "edge of the first component".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 42 recites the limitation "the edge" in the last line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claim 30 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the claim recites parts of the human body per se without referring to any related apparatus features. To overcome this rejection, the Examiner recommends changing the language of Claim 30 to read as follows "wherein the implantable medical device is adapted to be implanted on a cranium of a patient, and the overmold includes a cap to cover a hole through the cranium".

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-4, 12-14, 18, 47-48, 63 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singer et al. (U.S. 5,638,832) (herein Singer). As to Claims 1-2, 12 and 47-48, Singer discloses a subcutaneous implant, read as an implantable medical device 10 comprising a plurality of interconnected modules – control module 12 and display device 14, interconnected via electronic coupling 20 – each of the modules 12, 14 comprising a respective one of a plurality of housings (see Singer Abstract, Fig. 1, column 2, lines 38-50 and column 3, lines 2-3). Singer further discloses that the implantable medical device 10 may also comprise a biologically-inert substance, read as an overmold that at least partially encapsulates each of the housings and includes the electronic coupling, read as a motion reduction element 20. Specifically, Singer discloses that the modules 12 and 14 and the motion reduction element 20 may be located inside

a biologically-inert capsule (see Singer column 2, lines 51-55). The Examiner takes the position that motion reduction element 20 "reduces intermodule motion" since the element 20 connects the modules together and doesn't allow them to move apart from one another. Singer further discloses that it is desirable for a portion of the implantable medical device to be "flexibly constructed in order to conform to the surface of the skin 16". It is evident from Singer Figs. 1 and 3-4 that a portion of the implantable medical device 10 is tapered to provide a sloped transition between an edge of the implantable medical device 10 and a surface (i.e. the skin 16) of the patient. It is also inherent or at least obvious that in an embodiment of the device 10 that is "encapsulated", the encapsulation, read as the overmold, would also be tapered to provide such a sloped transition (see Singer Figs. 1 and 3-4 column 1, lines 66-67, column 2, lines 1-2 and column 3, lines 9-16).

Singer specifies that it is preferable to design the device 10 to be flexible such that discomfort to the human receiving the implant is reduced (see Singer column 3, lines 9-16). Giving this, it would have been obvious to one having ordinary skill in the art to manufacture the device such that an angle that exists between the edge of the device 10 and the surface of the patient is at an optimal value for reducing patient discomfort. Singer discloses the claimed invention as discussed above except that it is not specified that an angle between the edge of the overmold of the implantable medical device 10 and the surface of the patient is greater than 90 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the angle between the edge of the implantable medical device 10 and the surface of the patient is greater than 90 degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

12. As to Claims 3 and 4, Singer discloses that it is desirable for the encapsulated device 10 to be flexible (see Singer column 1, lines 66-67, column 2, lines 1-2 and 51-55 and column 3, lines 9-16). Singer discloses the claimed invention as discussed above except it is not specified that the biologically-inert encapsulation, read as the overmold comprise an elastomeric material such as silicone. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the overmold out of an elastomer such as silicone, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

13. As to Claim 13, Singer discloses the claimed invention as discussed above except that it is not specified that an angle between the edge of the overmold of the implantable medical device 10 and the surface of the patient be within a range from 120 to 150 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the angle formed with a range from 120 to 150 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

14. As to Claim 14, Singer discloses the claimed invention as discussed above except that it is not specified that an angle between the edge of the overmold of the implantable medical device 10 and the surface of the patient be approximately equal to 135 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the angle between the edge of the implantable medical device 10 and the surface of the patient be approximately equal to 135 degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

15. As to Claims 18, 63 and 66, it is evident from Singer Figs. 1 and 3-4 that a portion of the implantable medical device 10 is "concave" to provide a sloped transition between an edge of the implantable medical device 10 and a surface (i.e. the skin 16) of the patient. It is also inherent or at least obvious that in an embodiment of the device 10 that is "encapsulated", the encapsulation, read as the overmold, would also be "concave" to provide such a sloped transition (see Singer Figs. 1 and 3-4 column 1, lines 66-67, column 2, lines 1-2 and column 3, lines 9-16). The Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the encapsulation of device 10, read as the overmold as discussed above is capable of conforming substantially to a cranium of a patient.

16. Claims 1, 5, 7, 10-14, 18-19, 21, 31, 47, 51, 63 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Probst et al. (U.S. 7,103,415) (herein Probst). As to Claims 1, 12-14 and 47, Probst discloses an implantable medical device 10 comprising an electrochemical cell 12, read as a module and control circuitry 32, read as another module. Probst expressly discloses that the module 12 comprises a casing, read as a housing 14. Although silent to module 32 comprising a specified "housing", it is inherent or at least obvious to one having ordinary skill in the art that module 32 also comprising a housing to protect whatever chips, resistors and other miscellaneous electrical components that exist within the module 32 and the Examiner makes reference to Probst Fig. 1. Probst discloses that the implantable medical device 10 further comprises a housing, read as an overmold 36 that at least partially encapsulates each

of the modules 12 and 32. Probst specifies that modules 12, 32 are interconnected by lead 34. The Examiner takes the position that lead 34 is synonymous with Applicant's "motion reduction element to reduce intermodule motion" since lead 34 keeps the two modules 12 and 32 connected to each other and unable to move apart. Probst also discloses that an edge of the overmold 36 is tapered to provide a sloped transition between the implantable medical device 10 and a surface of the patient (see Probst Figs. 1-8, column 2, lines 20-67, columns 3-5 and column 6, lines 1-15).

Probst discloses the claimed invention as discussed above except that it is not specified that an angle between the edge of the overmold 36 and a surface of the patient be greater than 90 degrees, within a range from 120 to 150 degrees or approximately equal to 135 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device 10 such that an angle between the edge of the overmold 36 and a surface of the patient is greater than 90 degrees, within a range from 120 to 150 degrees or approximately equal to 135 degrees, since it has been held that where the general conditions of a claim are discloses in the prior art, discovering an optimum or workable range involves only routine skill in the art. Furthermore, Probst discloses that the implantable medical device 10 of the invention disclosed applies to "hearing-assist devices, artificial hearts, neurostimulators, drug pumps, cardiac pacemakers, cardiac defibrillators and heart-assist devices" and that it is desirable for the device 10 to be "shaped or contoured to more closely fit the curved shape of the body". It would have been obvious to one having ordinary skill in the art to determine the degree of arc or contour that the device 10 should have depending on its use and where it is to be implanted within a patient (see Probst column 1, lines 13-50)

17. As to Claim 5, Probst discloses that the overmold 36 may comprise non-elastomeric materials such as nickel, aluminum, stainless steel, mild steel, tantalum or titanium (see Probst column 2, lines 20-26).

18. As to Claim 7, Probst discloses another embodiment of the device having a housing, read as an overmold 60 (see Probst Fig. 2A) where the overmold 60 comprises a deep drawn unitary member including front and back side walls 62 and 64, right and left end walls 66 and 68 and bottom wall 70. The Examiner takes the position that the deep drawn unitary member is synonymous with "a first component of the overmold" since the member at least partially encapsulates each of the housings of modules 12 and 32. Overmold 60 also comprises a lid, read as a second component 74, which is positioned over opening 72 to surround the housings of modules 12 and 32 (see Probst column 3, lines 17-50).

19. As to Claims 10 and 51, Probst discloses feedthrough wires 50 and 52 and seals 54 and 56, collectively read as a "lead connection module" within the overmold 36 for connecting an external lead to the electronics within the control circuit module 32 (see Probst Fig. 1, column2, lines 66-67 and column 3, lines 1-9).

20. As to Claim 11, Probst discloses another embodiment of the device having a housing, read as an overmold 60 (see Probst Fig. 2A) where the overmold 60 comprises a deep drawn unitary member including front and back side walls 62 and 64, right and left end walls 66 and 68 and bottom wall 70. The Examiner takes the position that the deep drawn unitary member is synonymous with "a first overmold" since the member at least partially encapsulates each of the housings of modules 12 and 32. Overmold 60 also comprises a lid, read as a second overmold 74, which is positioned over opening 72 to surround the housings of modules 12 and 32. Second

overmold 74 also encapsulates feedthrough wires 84 and 86 and seals 88 and 90, collectively read as a "lead connection module" (see Probst column 3, lines 17-50).

21. As to Claims 18, 63 and 66, in addition to the arguments presented above, Probst discloses that the overmold 36 of the device 10 is concave. The Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the surface is capable of being a cranium and furthermore, the overmold 36 of device 10 is capable of conforming substantially to a cranium of a patient (see Probst Figs. 1-8, column 1, lines 13-50, column 2, lines 20-67, columns 3-5 and column 6, lines 1-15).

22. As to Claim 19, in addition to the arguments presented above, the Examiner takes the position that the overmold 36 of the device 10 is molded prior to implantation since the overmold 36 is manufactured of non-flexible and non-malleable materials like nickel, aluminum, stainless steel, mild steel, tantalum or titanium (see Probst column 2, lines 20-26).

23. As to Claim 21, Probst discloses that the overmold 36 may comprise non-elastomeric materials such as nickel, aluminum, stainless steel, mild steel, tantalum or titanium (see Probst column 2, lines 20-26). It is inherent that such metallic materials have high thermal conductivity. The Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The overmold 36 of Probst is

capable of acting as a heat sink for thermal energy generated within the modules since it may comprise these metallic materials.

24. As to Claim 31, Probst discloses that the device 10 may be a neurostimulator. It is inherent that in this application/embodiment the control circuit module 32 would provide neurostimulation therapy to a patient (see Probst Figs. 1-8, column 1, lines 13-50, column 2, lines 20-67, columns 3-5 and column 6, lines 1-15).

25. Claims 1, 2, 5, 10, 12-14, 23-25, 47-48, 51 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muto (U.S. 4,094,321). As to Claims 1, 12-14 and 47, Muto discloses an implantable medical device 30 comprising a plurality of interconnected modules 31 and 32. Muto specifies that each of the modules 31 and 32 are "self-contained" which the Examiner is interpreting as each module comprises a respective one of a plurality of housings. Muto further discloses that the device 30 comprises a hollow casing, read as an overmold, 42 that at least partially encapsulates each of the housings of the interconnected modules 31 and 32. Muto further specifies that an edge of the overmold 42 is tapered to provide a sloped transition between the device 30 and a surface of the patient. The Examiner takes the position that it is inherent or at least obvious that one or both of the modules 31 and 32 are glued or mounted to the bottom wall 43 of the overmold 42 as well known in the art and the Examiner makes reference to Muto Fig. 8. Gluing or mounting individual components to an interior wall of an implantable medical device housing or overmold is well known and obvious to one having ordinary skill in the art so that the components are not free to move and bang into one another within the housing or overmold of the device (see Muto Abstract, Figs. 1 and 6-8, column 1, lines 41-68, column 2, lines 1-10 and lines 35-64).

Muto discloses the claimed invention as discussed above except that it is not specified that an angle between the edge of the overmold 42 and the surface of the patient be greater than 90 degrees, within a range from 120 to 150 degrees or approximately equal to 135 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device 30 such that an angle between the edge of the overmold 42 and a surface of the patient is greater than 90 degrees, within a range from 120 to 150 degrees or approximately equal to 135 degrees, since it has been held that where the general conditions of a claim are discloses in the prior art, discovering an optimum or workable range involves only routine skill in the art.

26. As to Claims 2 and 48, Muto discloses that the overmold may be made of epoxy, which is considered to be flexible (see Muto column 2, lines 53-56).

27. As to Claim 5, Muto discloses that the overmold may be made of metal, which is considered to be a non-elastomeric material (see Muto column 2, lines 53-56).

28. As to Claims 10 and 51, Muto discloses that the device 30 further comprises (within the overmold 42) a female catheter connection element 33, including a socket 34 having an opening 35 and a clamp screw 36, transversely threaded for releasable securing a prong 37 of a catheter lead 38. Female catheter connection element 33, including a socket 34 having an opening 35 and a clamp screw 36 are collectively read as a "lead connection module" (see Muto column 2, lines 35-46).

29. As to Claim 23, Muto discloses that the device 30 further comprises (within the overmold 42) a female catheter connection element 33, including a socket 34 having an opening 35 and a clamp screw 36, transversely threaded for releasable securing a prong 37 of a catheter lead 38.

Female catheter connection element 33, including a socket 34 having an opening 35 and a clamp screw 36 are collectively read as an "external lead management structure" for an external lead 38 being routed away from the implantable medical device 30 (see Muto column 2, lines 35-46). Muto discloses the claimed invention as discussed above except that there is only one lead 38 being routed away from the device 30. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the device comprise more than one female catheter connection element, including a socket having an opening and a clamp screw for routing more than one lead away from the device, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art.

30. As to Claims 24 and 53, Muto discloses that the overmold 42 includes a groove 58 to hold external lead material (see Muto Fig. 2 and column 3, lines 9-31).

31. As to Claim 25, Muto discloses the claimed invention as discussed above except it is not disclosed that the overmold include a "pouch" to hold external lead material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Muto with a "pouch" for holding external lead matrial, because Applicant has not disclosed that a pouch provides an advantage, is used for a particular purpose, or solves a stated problem. One or ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the groove system 58 as taught by Muto, because it provides a means for holding external lead material and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Muto.

Therefore, it would have been an obvious matter of design choice to modify Muto to obtain the invention as specified in the claim(s).

32. Claims 3-4, 6, 20, 22 and 49 rejected under 35 U.S.C. 103(a) as being unpatentable over Muto in view of Bardy et al. (U.S. 6,788,974) (herein Bardy). As to Claims 3 and 4, Muto discloses that the overmold 42 may be made of metal or epoxy or of any other suitable inert coating used to encapsulate an implantable medical device 30 (see Muto column 2, lines 53-56). Applicant differs from Muto in that the overmold of the device is specified to be made of elastomeric silicone. The Examiner considers the use of silicone as an overmold to encapsulate an implantable medical device to be conventional and well known in the art with Bardy being but one example. Bardy discloses a curved and/or concave implantable medical device (S-ICD or US-ICD) comprising a hermetically sealed housing, read as an overmold 192 that encases the electronics for the canister 190 (see Bardy Fig. 19 and column 14, lines 38-42). In reference to Bardy Figs. 19-21 and 26A-26C, the overmold 192, 280 of the canister of the S-ICD is depicted as having a distal portion that is tapered to provide a sloped transition between the edge of the implantable medical device and a surface of a patient (see Bardy Figs. 19-20 and column 14, lines 18-37, column 23, lines 6-52 and column 30, lines 14-29). Bardy discloses that the overmold 192 of the canister 190 may comprise elastomeric silicone (see Bardy column 16, lines 31-35).

33. As to Claim 6, Muto discloses that the overmold 42 may be made of metal or epoxy or of any other suitable inert coating used to encapsulate an implantable medical device 30 (see Muto column 2, lines 53-56). Applicant differs from Muto in that the overmold of the device is specified to be made of non-elastomeric polysulfone or polyurethane. The Examiner considers the use of materials such as polysulfone or polyurethane for encapsulating an implantable medical device to be conventional and well known in the art with Bardy being but one example.

Bardy discloses a curved and/or concave implantable medical device (S-ICD or US-ICD) comprising a hermetically sealed housing, read as an overmold 192 that encases the electronics for the canister 190 (see Bardy Fig. 19 and column 14, lines 38-42). In reference to Bardy Figs. 19-21 and 26A-26C, the overmold 192, 280 of the canister of the S-ICD is depicted as having a distal portion that is tapered to provide a sloped transition between the edge of the implantable medical device and a surface of a patient (see Bardy Figs. 19-20 and column 14, lines 18-37, column 23, lines 6-52 and column 30, lines 14-29). Bardy discloses that the overmold 192 of the canister 190 may comprise a non-elastomeric material such as polyurethane (see Bardy column 16, lines 31-35).

34. As to Claims 20 and 49, Muto discloses that the overmold 42 may be made of metal or epoxy or of any other suitable inert coating used to encapsulate an implantable medical device 30 (see Muto column 2, lines 53-56). Muto discloses the claimed invention as discussed above except that it is not specified that the material of the overmold 42 be "durometer specific".

Bardy, however, discloses a curved and/or concave implantable medical device (S-ICD or US-ICD) comprising a hermetically sealed housing, read as an overmold 192 that encases the electronics for the canister 190 (see Bardy Fig. 19 and column 14, lines 38-42). In reference to Bardy Figs. 19-21 and 26A-26C, the overmold 192, 280 of the canister of the S-ICD is depicted as having a distal portion that is tapered to provide a sloped transition between the edge of the implantable medical device and a surface of a patient (see Bardy Figs. 19-20 and column 14, lines 18-37, column 23, lines 6-52 and column 30, lines 14-29). Bardy discloses that the primary function of the overmold 192 is to provide a protective barrier between the modules held within its confines and the surrounding environment and that the overmold 192 must possess sufficient

hardness to protect its contents and sufficient pliability of flexible characteristics to enable the overmold 192 to partially yield with its overall form without fracturing (see Bardy column 15, lines 61-67 and column 16, lines 1-6). The Examiner considers many of the materials sufficient for the overmold 192 listed at Brady column 16, lines 31-48 to be durometer specific for comprising both sufficient hardness and sufficient flexibility. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the overmold of Muto in view of Bardy to be made from a durometer specific material such that the overmold is capable of providing a protective barrier between the modules held within its confines and the surrounding environment and so that the overmold may possess sufficient hardness to protect its contents and sufficient pliability of flexible characteristics to enable the overmold to partially yield with its overall form without fracturing.

35. As to Claim 22, Muto discloses that the overmold 42 may be made of metal or epoxy or of any other suitable inert coating used to encapsulate an implantable medical device 30 (see Muto column 2, lines 53-56). Applicant differs from Muto in that the overmold of the device is specified to be made of a material having a low thermal conductivity. The Examiner considers the use of materials having low thermal conductivities to encapsulate an implantable medical device to be conventional and well known in the art with Bardy being but one example. Bardy discloses a curved and/or concave implantable medical device (S-ICD or US-ICD) comprising a hermetically sealed housing, read as an overmold 192 that encases the electronics for the canister 190 (see Bardy Fig. 19 and column 14, lines 38-42). In reference to Bardy Figs. 19-21 and 26A-26C, the overmold 192, 280 of the canister of the S-ICD is depicted as having a distal portion that is tapered to provide a sloped transition between the edge of the implantable medical device

and a surface of a patient (see Bardy Figs. 19-20 and column 14, lines 18-37, column 23, lines 6-52 and column 30, lines 14-29). Bardy discloses that the overmold 192 may comprise a ceramic such as zirconium ceramics and aluminum-based ceramics (see Bardy column 16, lines 35-37). It is inherent that ceramic materials have low thermal conductivity.

36. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muto in view of Loeb et al. (U.S. 6,214,032) (herein Loeb). As to Claim 28, Applicant differs from Muto in that the device comprises a radio-opaque marker within the overmold. The Examiner considers the use of such markers for the purpose of fluoroscopic imaging for visualization of placement to be conventional and well known in the art with Loeb being but one example (see Loeb column 7, lines 46-50).

37. As to Claim 29, Muto discloses the claimed invention as discussed above except that it is not disclosed that the overmold 42 is impregnated with a therapeutic agent. Loeb, however, discloses a microstimulator, read as an implantable medical device 18 comprising a glass or ceramic capsule 2 and a coating, read as an overmold 10 impregnated with a therapeutic agent 20 such as an anti-inflammatory antibiotic agent intended to reduce the foreign body reaction (see Loeb Fig. 3, column 5, lines 10-15, lines 24-34 and lines 40-67, column 6, lines 1-7 and lines 13-16, column 7, lines 51-62, column 8, lines 57-67 and column 9, lines 1-7). Loeb further discloses that the silicone elastomer or thermoplastic overmold 10 impregnated with such therapeutic agents 20 provides an implantable medical device 18 which is selected to produce desired physiological effects (depending on the type of agent 20 used) and to aid, support or to supplement the effects of the electrical stimulation and to, as previously mentioned, prevent or reduce foreign body reaction (see Loeb Abstract, column 8, lines 57-67 and column 9, lines 1-

7). The Examiner considers the implantable medical device 30 of Muto to be synonymous with the implantable medical device 18 of Loeb since both are adapted for implantation beneath the skin of a patient and both are for applying therapeutic electrical stimulation to a patient from the implanted position. Therefore, it would have been obvious to one having ordinary skill in the art to modify the overmold of Muto in view of Loeb to be impregnated with a therapeutic agent to provides an implantable medical device which is selected to produce desired physiological effects (depending on the type of agent used) and to aid, support or to supplement the effects of the electrical stimulation and to prevent or reduce foreign body reaction to improve the overall implantation and effectiveness of the implant.

38. Claims 27 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muto in view of Sanchez-Zambrano (U.S. 5,895,414). Applicant differs from Muto in that the overmold includes a through-hole to receive an attachment mechanism for attaching the implantable medical device to a patient. The Examiner considers such "through-holes" to be conventional and well known in the art with Sanchez-Zambrano being but one example. Sanchez-Zambrano discloses a curved and/or concave implantable medical device 11 which includes mounting means 35 and 39 (preferably apertures, read as "through-holes") within its housing, read as its overmold for receiving attachment mechanisms like sutures (see Sanchez-Zambrano Figs. 1-3 and column 2, lines 16-39).

Double Patenting

39. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

40. Claims 1-8, 10-34, 36-45, 47-49, 51, 53-56 and 60-66 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 (Amended November 16, 2005) of copending Application No. 10/731,638. Although the conflicting claims are not identical, they are not patentably distinct from each other because the

current claims are a broadening of the scope of the claims presented in Application No. 10/731,638 or an obvious variant thereof. The Examiner makes reference to the Applicant's disclosure (of the current Application) pages 16-17, paragraphs 63-64 where it is specified that the "motion reduction element" is synonymous with one that allows multiple degrees of movement along multiple axes to occur between the modules.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

41. Claims 1-8, 10-34, 36-45, 47-49, 51, 53-56 and 60-66 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 and 26-31 (Amended June 27, 2006) of copending Application No. 10/731,867. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are a broadening of the scope of the claims presented in Application No. 10/731,867 or an obvious variant thereof. The Examiner makes reference to the Applicant's disclosure (of the current Application) pages 16-17, paragraphs 63-64 where it is specified that the "motion reduction element" is synonymous with one that allows multiple degrees of movement along multiple axes to occur between the modules.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

42. Claims 1-8, 10-34, 36-45, 47-49, 51, 53-56 and 60-66 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31 and 33-57 (Amended November 28, 2005) of copending Application No. 10/731,869. Although the conflicting claims are not identical, they are not patentably distinct from each other

because the current claims are a broadening of the scope of the claims presented in Application No. 10/731,869 or an obvious variant thereof. The Examiner makes reference to the Applicant's disclosure (of the current Application) pages 16-17, paragraphs 63-64 where it is specified that the "motion reduction element" is synonymous with one that allows multiple degrees of movement along multiple axes to occur between the modules.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

43. Claims 1-8, 12-22, 31, 32-34, 36, 39-41, 45, 47-49, 56, 60-61, 63, 64 and 66 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 10/731,881 in view of Bardy. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either a broadening of the scope of the patented claims or an obvious variant thereof. Application No. 10/731,881 claims the claimed invention as discussed above except that it is not specified that the "member" is flexible and tapered to provide a smooth transition between an edge of the device and a surface of a patient.

Bardy, however, discloses an implantable medical device (S-ICD or US-ICD) comprising a battery supply, capacitor and operational circuitry (see Bardy column 5, lines 10-18 and column 14, lines 42-45). Bardy further discloses that the canister 190 of the implantable medical device (S-ICD or US-ICD) comprises a hermetically sealed housing, read as an overmold 192 that encases the electronics for the canister 190 (see Bardy Fig. 19 and column 14, lines 38-42). In reference to Bardy Figs. 19-21 and 26A-26C, the overmold 192, 280 of the canister of the S-ICD is depicted as having a distal portion that is tapered to provide a sloped transition between

the edge of the implantable medical device and a surface of a patient (see Bardy Figs. 19-20 and column 14, lines 18-37, column 23, lines 6-52 and column 30, lines 14-29).

Bardy further discloses that it is preferable to make the device have a "malleable canister", read as a "malleable overmold" that can conform to the desired shape of the implantation site on a patient (see Bardy column 6, lines 39-45) for comfortable long term implantation (see Bardy column 3, lines 16-26). The Examiner takes the position that a "malleable overmold" is synonymous with an overmold that is "flexible". The Examiner also takes the position that the device of Application No. 10/731,881 is synonymous with the device of Bardy since both are implantable electrostimulating devices. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the claims of Application No. 10/731,881 in view of Bardy to be include a tapered, flexible member since such a modification would provide a device that is malleable, flexible and pliable to ensure comfortable and long-term implantation of the device in a patient.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

44. Applicant's arguments with respect to claims 1-8, 10-34, 36-45, 47-49, 51, 53-56 and 60-66 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

45. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

Engmark et al. (U.S. 2004/0082977) discloses an implantable medical device that includes an overmold and an intermodule motion reduction element.

46. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The Examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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